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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,262	02/18/2004	Geoffrey Smith	BWT-PT001.2	3996

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,262	SMITH ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 10 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed June 28, 2007 in response to the Office Action of January 24, 2007 is acknowledged and has been entered. Claims 2-9 have been canceled. New claims 12-15 have been added. The rejections of the canceled claims 2-9 are moot. A new 892 form is attached listing the correct US Patent number that was cited in non-final action of 1/24/2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1 and 10 and new claims 12-15 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained**.

New claims 12-15 are drawn to the a medicament for use in treatment and prophylaxis according to claim 1, comprising a recombinant poxvirus, which is genetically engineered to be incapable of expressing a native A41L protein, wherein the recombinant poxvirus is a genetically engineered MVA virus. New claims 12-15 are rejected on the same grounds as claims 1 and 10, because the claims are drawn to a medicament for use in treatment and prophylaxis.

Applicant's arguments have been fully considered but fail to persuade. Applicants argue that the claimed medicament comprising a recombinant poxvirus, which is genetically engineered to be incapable of expressing a native A41L protein is enabled because Applicants have tested the claimed medicament in an acceptable animal model and have shown that the

deletion of the A41L gene resulted in enhanced immune responses to the poxvirus as compared to the immune response generated by immunization with poxvirus vaccine that comprises the A41L gene. Applicants also submit that deletion of A41L gene from poxvirus could improve the immunogenicity of the poxvirus expressing heterologous genes. Applicants direct to the reference by Clark et al., filed as an Exhibit, and point out that Clark et al. show that deletion of A41L from MVA improves vaccine efficacy *in vivo*.

In response to Applicants arguments the Office acknowledges that the smallpox vaccine known in the art (disclosed in US Patent 4,722,848), as well as the recombinant vaccinia virus incapable of expressing a native A41L protein of the present invention are effective in generation of immune responses in mammals. It is also acknowledged that an effective smallpox vaccine has been known and developed in the art at least 15 years before the priority of the present invention, as argued by the Applicant. It is however noted that the present claims are drawn to a medicament for use in treatment and prophylaxis, which encompasses preventing disease. While the claims are enabled for inducing an immunogenic response, the claims do not recite immunogenic compositions.. Further, while the poxvirus vaccine known in the art, has been known to effectively prevent the infection with a poxvirus, the poxvirus vaccine (the commercially available one) has not been used or shown effective in treatment or cure for existing poxvirus infection or any other disease. The skilled artisan would recognize that a poxvirus vaccine would not be beneficial for treatment of already existing infection or for treatment of other diseases. While the Applicants have shown that the present composition is effective for induction of immune responses, the Applicants have not shown that the present composition can be used for treatment of existing infections or treatment of other diseases.

Therefore, it is herein determined that Applicant's specification does not provide an adequate enablement for the claimed medicament.

With regard to the reference by Clark et al., the reference shows generation of protective immune responses by immunization of mice with vaccinia virus comprising a deletion of A41L gene. The reference does not provide a teaching evidencing that vaccinia virus comprising a deletion of A41L gene with or without a heterologous gene, can be successfully used as a medicament in treatment and/or prophylaxis of a disease.

Thus in view of the foregoing the rejection is maintained.

Rejection of claims 1 and 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of Applicant's arguments.

New rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "wherein the nucleotide sequences are set forth in SEQ ID NO: 1". There is insufficient antecedent basis for this limitation in the claim. Claim 14 depends from claim 13 that recites, "poxvirus is a genetically engineered through deletion of nucleotide sequences encoding the native A41L protein." Claim 13 from which claim 14 depends recites only one sequence, wherein claim 14 refers to sequences. It is not clear if Applicant intends that SEQ ID NO: 1 comprises more than one sequence. Correction and clarification is required.

Double Patenting Rejection

Rejection of claims 1 and 7-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,355,252 B1 **is maintained.**

Applicants state that Applicants will submit terminal disclaimer once the claims of the present application are indicated allowable.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AB

Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 9-17-2007
Primary Examiner, TC1600